REMARKS

Applicants respectfully request reconsideration and further examination of all pending claims presented herein.

I. Status of the Claims

Claims 1, 2 and 5-18 are currently pending in the application. Claims 6-15 have been withdrawn for being directed to a non-elected species and/or invention. Accordingly, claims 1, 2, 5 and 16-18 are currently under examination.

However, Applicants once again respectfully point out that, in view of the claim amendments previously presented (in Amendment D, submitted May 26, 2009), all claims now depend directly or indirectly from claim 1. Accordingly, Applicants request that withdrawn claims 6-15 be rejoined and examined, after claim 1 has been allowed.

II. Rejection under 35 U.S.C. §112, Second Paragraph

Applicants acknowledge withdrawal of the rejection of claims 1, 2, 5 and 16-18 under 35 U.S.C. §112(a) for omitting an autoclaving step.

III. Rejection under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1, 2, 5 and 16-18 as obvious under 35 U.S.C. §103(a) over the PET-Radiopharmaceutical Dispensing Unit Manual, Nuclear Interface GmbH ("the Manual"), including the Supplement FDG Synthesizers ("the Supplement") in view of Damhaut et al. (U.S. Patent No. 6,172,207) and further in view of Asai et al. (U.S. Patent No. 5,536,491) and Stone-Elander et al. (U.S. Patent No. 5,308,944).

A. Status of the Manual and Supplement as Prior Art

In response to Applicants' arguments regarding the prior art status of the Manual and Supplement as prior art, the Office asserts that (1) the scenarios offered by Applicants in which the Manual and Supplement were not disseminated are "hypothetical" and not based on any evidence, (2) the manual provides contact information including a phone number, fax number, website and email address which shows the manual was distributed to those skilled in the art,

and (3) the references should be considered because Applicants have admitted that it is material to patentability by citing it in the 12/4/05 Information Disclosure Statement.

In response to the Office's assertions in the Final Office action, Applicants respectfully reiterate their position as set forth in Amendment D (dated May 26, 2009). However, in the interests of brevity, Applicants will not restate the details of Amendment D in their entirety here. In addition, Applicants respectfully submit that, for the reasons set forth below, **the Office's positions are clearly contrary to law**.

Regarding the Office's assertions that the above-noted scenarios in which the Manual and Supplement were not distributed are only "hypothetical," Applicants submit that **it is not Applicants' burden** to establish that the document was not distributed, but rather **it is the Office's burden** to establish that the document was **actually distributed**. See *In re Wyer*, 655 F.2d 221, 227, 210 USPQ 790, 795 (CCPA 1981) cited in MPEP §2128 ("the one who wishes to characterize the information, in whatever form it may be, as a 'printed publication' . . . should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art."). Accordingly, the Office's opinion that the scenarios presented by the Applicants are merely hypothetical is **not relevant** to the issue. **The Office must establish that the reference was actually distributed, and it has simply failed to do so here**.

In support of Applicants' position, the Office's attention is called to *Resqnet.com, Inc., v. Lansa, Inc.* (533 F.Supp.2d 397). In this case, the alleged infringer argued that the patent at issue was invalid for being described in a printed publication before the critical date. The references at issue were a **user manual** that had a date of October 1991 on its first page and a **tutorial** that had a copyright date of 1993. According to the court, "no witness testified, nor was any evidence presented, that either of these documents was ever published or disseminated to the public." As a result, **the court held** that, in the absence of such evidence that the references were actually published or made public prior to the critical date, the references **could not** be considered prior art.[1]

In view of the foregoing, it is to be noted that the fact that the Manual being cited by the Office here includes a phone number, fax number, website and email is **clearly not evidence**

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1 It is to be noted that the court's position in the *Resqnet.com, Inc.* case is entirely consistent with the position taken by the Examiner during examination of the European application corresponding to the present U.S. application (now European Patent No. 1496946B1), the Examiner concluding there that insufficient evidence had been put forth to establish that the same references had actually been made available to the public. (See Applicants' Amendment D for additional details relating to the European Examiner's decision.)

that the reference was **actually disseminated** or otherwise made available. (*In re Wyer*, 665 F.2d 221, 227, 210 USPQ 790, 79 (CCPA 1981).)

Additionally, the alleged infringer in *Resqnet.com* also argued that submission by the patent owner of the references in an information disclosure statement during reexamination was an admission that the references were publicly disseminated. In contrast, the **U.S. Patent Office** noted, during the reexamination proceeding, that the "**mere submission of an IDS** to the USPTO **does not** constitute the patent Applicant's admission that any reference is in the IDS is prior art" (*Resqnet.com*, 533 F.Supp.2d 397, 414, note 5; citing *Abbott Lab. V. Baxter Pharm. Prods.*, 334 F.3d 1274, 1279 (Fed. Cir. 2003), emphasis added). Further, according to the court, submission of the reference in the IDS **does not speak to the dissemination of the reference prior to the critical date.**

With respect to the status of a reference as prior art as a result of it being submitted by Applicants in an IDS, it is to be noted that the court's position taken in *Resqnet.com*, as well as the position taken by the U.S. Patent Office during the reexamination proceeding detailed therein, is reinforced by the MPEP. Specifically, the Office's attention is called to MPEP §2129(IV), which states that the "[m]ere listing of a reference in an information disclosure statement **is not taken as an admission that the reference is prior art** against the claims." *Riverwood Int'l Corp. v R.A. Jones & Co.*, 324 F.3d 1346, 1354-55, 66 USPQ2d 1331, 1337-38 (Fed Cir. 2003) (Emphasis added.). Furthermore, 37 CFR 1.97(h) states, "The filing of an information disclosure statement **shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability** as defined in § 1.56(b)."

Accordingly, the Examiner's assertion that the Applicants "declared that the reference is considered material that is pertinent to patentability" based on the Applicants citation of the Manual in an information disclosure statement is clearly false. Furthermore, the Examiner's view is one that is has been explicitly rejected by both the U.S. Patent Office and the Federal Circuit Court of Appeals and is **not relevant** to whether the reference was **actually distributed**.

B. The Claimed Subject Matter

Claim 1 is directed to a method for improving radiostability of a ^{18}F-fluor-deoxy-glucose (^{18}F-FDG)-solution during autoclaving. The method of claim 1 as amended comprises the steps of: (a) providing a ^{18}F-fluor-deoxy-glucose (^{18}F-FDG)-solution; (b) adding at least one buffer based on a weak acid consisting of citrate, acetate, ascorbate and combinations thereof to the

^{18}F-fluor-deoxy-glucose (^{18}F-FDG)-solution; c) autoclaving the buffered ^{18}F-fluor-deoxy-glucose (^{18}F-FDG)-solution. As indicated in the specification (see, e.g., paragraphs [0003-0004] of the published application, U.S. Publication No. 2005/017553), Applicants have discovered a method for preparing a ^{18}F-fluor-deoxy-glucose (^{18}F-FDG)-solution that is sufficiently sterile and stable for use (i.e., for injection in a patient in need thereof). Sterilization is achieved by autoclaving a ^{18}F-fluor-deoxy-glucose (^{18}F-FDG)-solution that has been sufficiently buffered with a solution of a weak acid. In this way, a sterilized solution is obtained that still meets the specification of more than 95% radiochemical purity eight hours after production.

In view of Applicants' position that the Manual and Supplement are not prior art against the present application, Applicants will direct the remainder of their comments on the present rejection toward the combination of Damhaut et al., Asai et al and Stone-Elander et al. only. In the interest of brevity, Applicants will not repeat their arguments in favor of patentability or again characterize Damhaut et al., Asai et al. and Stone-Elander et al. but rather incorporate by reference the characterizations and arguments set forth in their previous Amendments and Letters to the USPTO.

C. Independent Claim 1 and Claims Depending Therefrom are not Obvious

Applicants submitted in Amendment D (filed May 26, 2009) that the Office failed to show that the prior art contained a method which differed from the claimed method by the substitution of some steps with other steps, that one of ordinary skill in the art would have substituted one known element for another, and that the results of the substitution would have been obvious. (See pages 9-10 of Amendment D.) Specifically, Applicants argued that the Office did not establish why the skilled artisan would be motivated to rearrange the steps of Damhaut et al. in addition to substituting the autoclaving step of Asai et al. for the filtration step of Damhaut et al. The Office has not directly addressed Applicants' argument, but rather has once again resorted to the use of the Manual in its rebuttal argument. However, Applicants have clearly established that the manual is **not prior art** against the present application.

Applicants also argued that Damhaut et al. teach away from use of an autoclaving step, as they disparage the use of process steps that require heating. In response to Applicants' argument, the Office submits that the reference of Damhaut et al. was not used to teach autoclaving, but rather was used to teach a citrate buffered 18F-FDG solution for NMR. Regardless of what purpose the Office is using the reference, the fact that it teaches away from using an autoclaving step is relevant. "A prior art reference must be considered in its entirety,

i.e., as a whole, **including portions that would lead away from the claimed invention**." (See, e.g., MPEP §2141.02(VI), emphasis added.) The Office cannot pick and choose which portions of Damhaut et al. may be ignored, and the fact that Damhaut et al. teach away from using an autoclaving step must be considered by the Office.

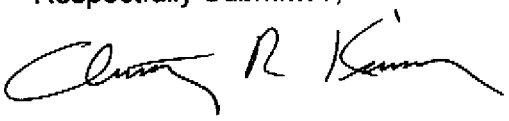
In view of the foregoing, the Office has clearly failed to establish a *prima facie* case of obviousness. Applicants therefore submit that the subject matter of claim 1, as well as all claims depending therefrom, is patentable over the cited references, both alone and in combination. Withdrawal of the present rejection is therefore requested.

CONCLUSION

In view of the foregoing, Applicants request favorable reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge Deposit Account No. 13-1160 for any fees that may be required for this Letter in the name of Mallinckrodt Inc.

Respectfully Submitted,



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